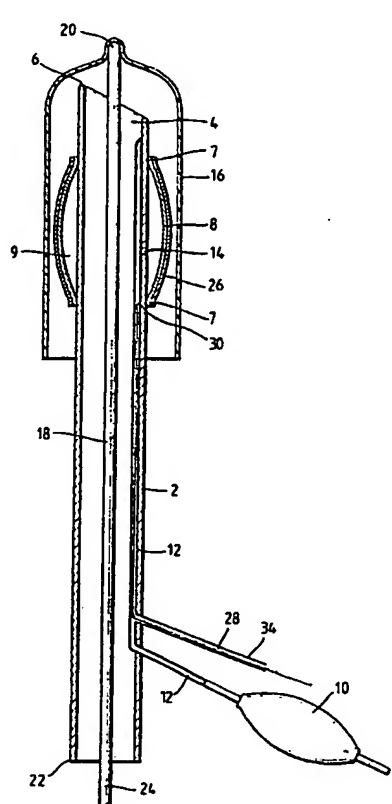


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INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

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(21) International Application Number: PCT/GB89/01484 (22) International Filing Date: 6 December 1989 (06.12.89) (30) Priority data: 8828778.4 9 December 1988 (09.12.88) GB (71) Applicant (for all designated States except US): WARNE SURGICAL PRODUCTS LIMITED [GB/GB]; Portadown Road, Lurgan, County Armagh BT66 8RD (GB). (72) Inventor; and (75) Inventor/Applicant (for US only) : PERRY, Colin, Edward [GB/GB]; 23 Bridgways, Banbridge, County Down BT32 4ED (GB). (74) Agent: ALLEN, Oliver, John, Richard; Lloyd Wise, Tregear & Co., Norman House, 105-109 Strand, London WC2R 0AE (GB).			(81) Designated States: AT (European patent), AU, BE (European patent), CH (European patent), DE (European patent), DK, ES (European patent), FI, FR (European patent), GB, IT (European patent), JP, LU (European patent), NL (European patent), NO, SE (European patent), US. Published <i>With international search report. Before the expiration of the time limit for amending the claims and to be republished in the event of the receipt of amendments.</i>
(54) Title: IMPROVEMENT IN AND RELATING TO CATHETER TUBES			
(57) Abstract <p>An endotracheal or tracheostomy tube wherein a fibre optic is located within a passage formed at or attached to the inner surface of the tube or within the tube wall. The passage serves to hold the fibre optic in position. The light emitting end of the fibre optic is suitably located adjacent to the end of the tube which is inserted into the trachea.</p>			
			

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Improvement in and Relating to Catheter Tubes

This invention relates to an endotracheal tube or catheter or to a tracheostomy tube.

Known endotracheal tubes comprise a length of flexible tubing which is inserted into the nasal passage or trachea. The tubes are often provided near the inserted end with an outer sleeve or balloon which is connected to a source of air or liquid so that it can be inflated when the tube is correctly positioned. The connection comprises a capillary tube secured along the internal surface of the endotracheal tube. One end of the capillary tube exits the endotracheal tube adjacent the insertion end and is connected to the source of air or liquid. The other end of the capillary tube is closed and is positioned near the inserted end. Air or liquid passes from the capillary tube to the balloon to inflate the latter through at least one suitable positioned hole in the endotracheal tube. The inflated balloon acts as a cushion to protect the internal tissues from traumatic damage and to hold the tube in place and also provides a gas seal to facilitate respiration by the ventilator.

It is also known to insert a fibre optic into the endotracheal tube to aid in correct insertion of the tube. With care the end of the fibre optic can be located adjacent the balloon so that by moving the tube until the light spot emitted by the end is in the desired position, the balloon can be inflated in the correct location.

This arrangement has several disadvantages. Firstly the fibre optic may partially block the flow of gas down the endotracheal tube. Secondly, endotracheal tubes are normally provided in a sterile condition, and insertion of the fibre optic violates the sterility. Thirdly a relatively large fibre optic is required to ensure that the light can be seen since dispersion of the light will occur due to the distance between the light emitting end and the

throat tissues. Finally, and as noted above, care is required to locate the fibre optic in the correct position and moreover, it is easy for the fibre optic to move during use of the endotracheal tube so giving a false locating image for the balloon position.

It is the object of this invention to provide an endotracheal tube which allows accurate location of the tube in the patient's trachea but which overcomes one or more of the above mentioned problems.

An endotracheal tube or tracheostomy tube in accordance with the invention comprises a fibre optic which is located within a passage formed at or attached to the internal surface of the tube or within the tube wall with the light emitting end of the fibre optic located adjacent the inserted end of the tube.

The arrangement allows the tube to be simply and accurately located in the patient's trachea since the fibre optic is held in position. The only movement of the spot of light emitted by the fibre optic will be due to movement of the tube itself so that any slippage of this from the desired location will be noticed and can be corrected. Since the fibre optic is held against the tube and therefore closely adjacent the throat there will be less dispersion of the light so that a smaller fibre optic can be employed which reduces the intrusion into the gas flow region. Moreover, the location of the fibre optic against the inner wall reduces to a minimum the chance of interruption of the gas flow down the tube. Finally the problems with sterility do not arise since the fibre optic is separated from the remainder of the interior surface of the tube by the passage.

Suitably the tube is provided with an outer sleeve towards the inserted end which is capable of being inflated with air or liquid once the tube has been positioned correctly. The sleeve acts to protect the internal tissue and hold the tube in place as well as providing a gas seal between the tube and the patient's trachea. The means for

inflating the sleeve preferably comprises a capillary tube secured along the interior surface of the tube. One end of the capillary tube is closed and is located adjacent the inserted end of the tube whilst the other end of the capillary tube which exits the endotracheal tube at or adjacent the insertion end is connected to the supply of liquid or air. At least one hole is provided in the endotracheal tube suitably located to allow passage of the air or liquid from the capillary tube to the sleeve.

Preferably the capillary tube also acts as the passage for the fibre optic. The amount of intrusion into the gas flow region is then reduced to a minimum.

Suitably the light emitting end of the fibre optic is bevelled to help direct light emission directly through the tissue.

The arrangement thus allows for accurate inspection of the throat tissue for damage without the need for a bronchoscope which could partially or fully block the tube especially since, as noted above, there is less diffusion of the light. Furthermore there is no need to x-ray the patient's trachea to determine the position of the tube which reduces costs and benefits the patient by reduction of the amount of radiation to which he or she is exposed.

The invention will now be further described by way of example with reference to the accompanying drawings in which:

Figure 1 is a longitudinal section through an endotracheal tube in accordance with the invention;

Figure 2 is a similar view to Figure 1 with the sleeve inflated and

Figure 3 is an enlarged cross-sectional view of part of a fibre optic particularly suitable for use in the tube of Figures 1 and 2.

The endotracheal tube comprises a length of flexible tubing 2, the inserted end 4 of which is cut

obliquely to form a mouth and is provided with rounded edges 6 for patient comfort.

Near the inserted end 4 of the tube 2, a sleeve or balloon 8 is provided around the tube, the ends 7 of the sleeve or balloon 8 being secured to the tube 2. Gas or liquid is supplied to the space 9 between the sleeve 8 and the tube 2 to inflate the sleeve 8 (see Figure 2) from an external pump 10 via capillary tube 12, secured to the interior surface of the tube or provided internally thereof, and an outlet 14 in the tube 2.

The sleeve 8 may be provided with a gas impermeable coating either externally, see 26, internally or both. This inhibits expansion of the sleeve due to permeation of gasses into the region 9 between the sleeve 8 and the tube 2 while the tube is in position which can lead to discomfort and damage to the patient. This is more fully described in co-pending Patent Application No. 8825236.6.

The endotracheal tube is shown in Figure 1 ready for insertion. A loose fitting cover 16 formed from a soft flexible material covers the mouth 4 and the sleeve 8. A tube 18, one end of which 20 is securely attached to the inside of the cover 16, extends through tube 2. The other end 24 of the tube protrudes from the insertion end 22 of the tube a sufficient distance to allow it to be firmly gripped.

The tube 2 is inserted into the nose or trachea and correctly position by monitoring the location of a spot of light emitted from the end of a fibre optic 28. The fibre optic 28 is located within the capillary tube 12 which holds it against the side of tube 2 to prevent it from obstructing gas flow through the tube. The light emitting end 30 of the fibre optic is shown located at the lower end of the sleeve 8 but it can be positioned in any desired location. The fact that the light emitting end 30 is close to the throat tissues means that there will be less dispersion than with known endotracheal tubes. The end 30

is preferably bevelled as shown in Figure 3 to take advantage of total internal reflection so that, as illustrated by beams 32, light emission is predominately directly radial of the tube through the tissue. The fibre optic can also be used to inspect throat tissue so obviating the need for a bronchoscope which may block the endotracheal tube.

The fibre optic exits the tube 2 via an aperture therein and is protected from damage by a cover 34.

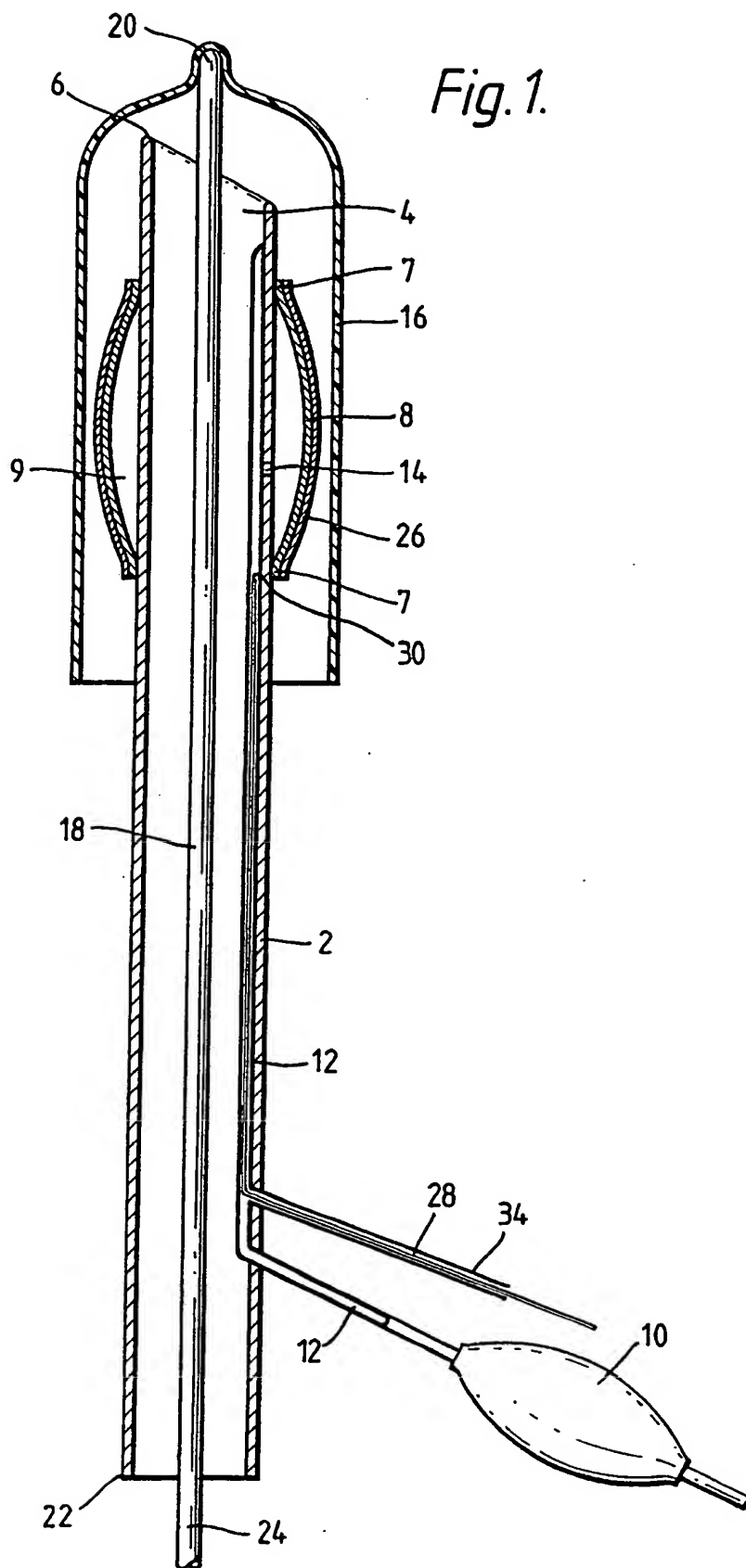
During insertion of the tube, mucus or other matter which might otherwise block the mouth of the tube is retained on the outer surface of the cover 16. The sleeve 8 is inflated by pumping the pump 10 and the cover 16 is removed by pulling protruding end 24 of the tube 18 to turn the cover 16 inside out thereby enclosing any retained mucus or the like so that this does not come into contact with the inner surface of the tube. A clear pathway to the lungs is therefore ensured.

Any movement out of the optimum position by the tube will be observed since, because the fibre optic is fixed in position, any change in position of the light spot will be due to tube spillage. The light spot will be clearly seen because firstly the reduced amount of dispersion and secondly the bevelled end. Thus the need to x-ray patients to determine the position of the tube (by means of an x-ray sensitive coating on the inserted end) is obviated with consequent advantages of cost and patient safety.

CLAIMS:

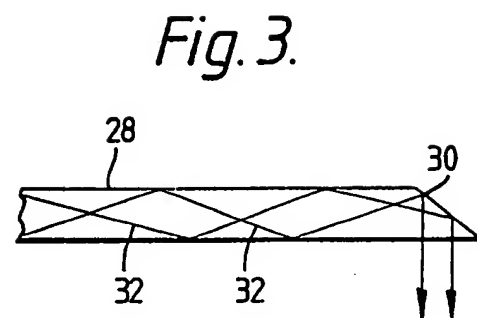
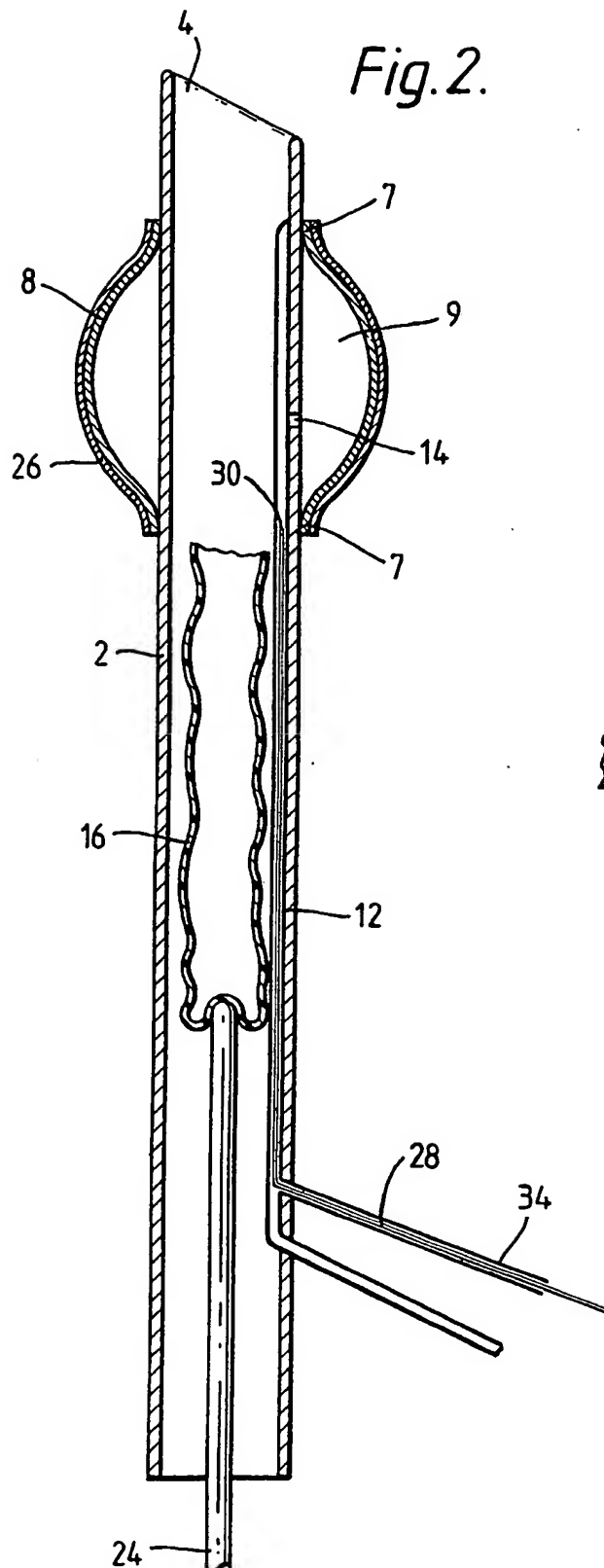
1. An endotracheal tube or tracheostomy tube comprising a fibre optic which is located within a passage formed at, or attached to, the internal surface of the tube or within the tube wall having the light emitting end of the fibre optic located adjacent to the inserted end of the tube.
2. A tube as claimed in Claim 1 wherein the light emitting end of the fibre optic is bevelled to direct light radially outwards through the throat tissue.
3. A tube as claimed in either Claim 1 or 2 including an outer sleeve near the inserted end of the tube, means being provided to inflate the sleeve with a fluid.
4. A tube as claimed in Claim 3 wherein the inflation means comprises a capillary tube, one end of which is closed, the other end of which communicates with a fluid source, a hole being provided to allow passage of the fluid from the capillary tube to the sleeve.
5. A tube as claimed in Claim 4 wherein the capillary tube acts as the passage for the fibre optic.
6. A tube as claimed in either Claim 4 or 5 wherein the capillary tube is secured along the interior surface of the endotracheal tube.
7. An endotracheal or tracheostomy tube substantial as described herein with reference to the accompanying drawings.

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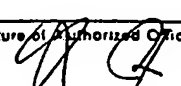
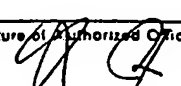
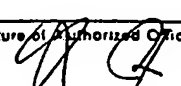
SUBSTITUTE SHEET

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INTERNATIONAL SEARCH REPORT

International Application No **PCT/GB 89/01484**

I. CLASSIFICATION OF SUBJECT MATTER (if several classification symbols apply, indicate all) ⁶ According to International Patent Classification (IPC) or to both National Classification and IPC IPC5: A 61 B 1/06, A 61 M 16/04, 25/00, 29/02														
II. FIELDS SEARCHED <div style="text-align: right; font-size: small;">Minimum Documentation Searched ⁷</div> <table style="width: 100%; border: none;"> <tr> <td style="width: 50%; border: none;">Classification System ¹</td> <td style="width: 50%; border: none;">Classification Symbols</td> </tr> <tr> <td style="border: none; height: 40px; vertical-align: top;"> IPC5 </td> <td style="border: none; height: 40px; vertical-align: top;"> A 61 B; A 61 M </td> </tr> </table> <div style="text-align: center; font-size: x-small;">Documentation Searched other than Minimum Documentation to the Extent that such Documents are Included in the Fields Searched ⁸</div>			Classification System ¹	Classification Symbols	IPC5	A 61 B; A 61 M								
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IPC5	A 61 B; A 61 M													
III. DOCUMENTS CONSIDERED TO BE RELEVANT ⁹ <table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th style="width: 10%; font-size: x-small;">Category ¹⁰</th> <th style="width: 60%; font-size: x-small;">Citation of Document, ¹¹ with indication, where appropriate, of the relevant passages ¹²</th> <th style="width: 30%; font-size: x-small;">Relevant to Claim No. ¹³</th> </tr> </thead> <tbody> <tr> <td style="text-align: center; vertical-align: top;">X</td> <td style="vertical-align: top;"> EP, A2, 0177124 (SUMITOMO ELECTRIC INDUSTRIES LIMITED) 9 April 1986, see page 3, line 32 - page 4, line 16; figure 1 <div style="text-align: center;">--</div> </td> <td style="vertical-align: top; text-align: center;">1,3-6</td> </tr> <tr> <td style="text-align: center; vertical-align: top;">X</td> <td style="vertical-align: top;"> US, A, 4041936 (CARDEN) 16 August 1977, see column 2, line 3 - line 25; figures 1-2 <div style="text-align: center;">--</div> </td> <td style="vertical-align: top; text-align: center;">1,3,4</td> </tr> <tr> <td style="text-align: center; vertical-align: top;">X</td> <td style="vertical-align: top;"> US, A, 4567882 (HELLER) 4 February 1986, see column 3, line 15 - column 4, line 56; figures 1-4 <div style="text-align: center;">--</div> <div style="text-align: center;">-----</div> </td> <td style="vertical-align: top; text-align: center;">1-2,5,6</td> </tr> </tbody> </table>			Category ¹⁰	Citation of Document, ¹¹ with indication, where appropriate, of the relevant passages ¹²	Relevant to Claim No. ¹³	X	EP, A2, 0177124 (SUMITOMO ELECTRIC INDUSTRIES LIMITED) 9 April 1986, see page 3, line 32 - page 4, line 16; figure 1 <div style="text-align: center;">--</div>	1,3-6	X	US, A, 4041936 (CARDEN) 16 August 1977, see column 2, line 3 - line 25; figures 1-2 <div style="text-align: center;">--</div>	1,3,4	X	US, A, 4567882 (HELLER) 4 February 1986, see column 3, line 15 - column 4, line 56; figures 1-4 <div style="text-align: center;">--</div> <div style="text-align: center;">-----</div>	1-2,5,6
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<div style="display: flex; justify-content: space-between; font-size: x-small;"> <div style="width: 45%;"> <p>¹⁴ Special categories of cited documents: ¹⁰</p> <p>"A" document defining the general state of the art which is not considered to be of particular relevance</p> <p>"E" earlier document but published on or after the international filing date</p> <p>"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)</p> <p>"O" document referring to an oral disclosure, use, exhibition or other means</p> <p>"P" document published prior to the international filing date but later than the priority date claimed</p> </div> <div style="width: 45%;"> <p>"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention</p> <p>"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step</p> <p>"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.</p> <p>"&" document member of the same patent family</p> </div> </div>														
IV. CERTIFICATION <table style="width: 100%; border: none;"> <tr> <td style="width: 50%; border: none; vertical-align: top;"> Date of the Actual Completion of the International Search 16th March 1990 </td> <td style="width: 50%; border: none; vertical-align: top;"> Date of Mailing of this International Search Report 10. 04. 90 </td> </tr> <tr> <td style="border: none; vertical-align: top;"> International Searching Authority EUROPEAN PATENT OFFICE </td> <td style="border: none; vertical-align: top;"> Signature of Authorized Officer <div style="text-align: center;">  L. ROSSI </div> </td> </tr> </table>			Date of the Actual Completion of the International Search 16th March 1990	Date of Mailing of this International Search Report 10. 04. 90	International Searching Authority EUROPEAN PATENT OFFICE	Signature of Authorized Officer <div style="text-align: center;">  L. ROSSI </div>								
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**ANNEX TO THE INTERNATIONAL SEARCH REPORT
ON INTERNATIONAL PATENT APPLICATION NO. PCT/GB 89/01484**

SA 33087

This annex lists the patent family members relating to the patent documents cited in the above-mentioned international search report.
The members are as contained in the European Patent Office EPP file on 28/02/90
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Patent document cited in search report	Publication date	Patent family member(s)	Publication date
EP-A2- 0177124	09/04/86	CA-A- 1221496	05/05/87
		EP-A-B- 0136186	03/04/85
		JP-A- 60252602	13/12/85
		US-A- 4548689	22/10/85
		JP-A- 61085916	01/05/86

US-A- 4041936	16/08/77	NONE	

US-A- 4567882	04/02/86	NONE	
